JAN 0 8 2013

K121261

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

5.1 Applicant:

asap endoscopic products GmbH
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Contact Person : Horst Baholzer

5.2 Device Identification

Trade name: *asap multiscope*

Common name: Spinal Endoscope

Classification Name: Arthroscope and Accessoires (21 CFR 888.1100; Product Code HRX)

5.3 Predicate Devices

K051827: Joimax Tessys Multiscope

K061246: Arthro Kinetics Endoscopic Spine System

K083552: maxMorespine Endoscope

5.4 Description of Device

The *asap multiscope* is a rigid or semiflex-type multi-channel endoscope provided with a rod lens system to transmit light and images, a working channel and one or two irrigation channel(s) and stopcocks. The body consists of an outer and an inner tube of surgical steel. The light-carrying fibers are sandwiched between these tubes. The inner tube of the body contains the rod lens system, the working channel and the irrigation/suction channel(s). The eyepiece and light post are adaptable to standard endoscopic cameras and light systems. The endoscope is intended for use with standard working sheaths (cannulas) for minimally invasive access.
Accessories include working sheaths, spinal needles, guide wire, dilators, trephine, hammers, trocars, forceps, and rongeurs, as well as cleaning brushes, a rubber sealing cap, spare O-rings, and a protection sheath.

5.5 Indications for Use

The *asap multiscope* is intended to visualize the inside of the patient through a cannulated incision for diagnostic and surgical procedures, such as arthroplasty, nucleotomy, discec tomy, and foraminotomy.

5.6 Technological Characteristics

The *asap multiscope* is a multi-channel endoscope used to visualize the operative site and provided with a working channel and irrigation channel(s). It is a rigid or semiflex-type endoscope consisting of three basic components through which light is projected into the operation site and a video image is produced on an external video . The *asap multiscope* has a snap coupler or smart lock connector enabling replacement of the eyepiece by a standard camera.

5.7 Performance Data

Specifications and intended use of the *asap multiscope* are the same as those of the predicate devices. There are no significant differences between the *asap multiscope* and the predicates in design or usage conditions. Materials are identical to those of the predicate devices, ensuring high performance and biocompatibility.

The device will be sold non-sterile for steam sterilization by the user. The recommended cleaning and sterilization processes have been validated.

Performance testing was conducted according to the applicable sections of standard IEC 60601-2-18. Medical Electrical Equipment – Part 2: Particular Requirements for the Safety of Endoscopic Equipment.

5.8 Conclusions

The information provided in this 510(k) submission provides reasonable assurance that the *asap multiscope* is safe and effective and that it is substantially equivalent to the predicate devices with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ASAP Endoscopic Products GMBH
% Business Support International
Ms. Angelika Scherp
Regulatory Affairs Consultant
Amstel 320-I
Amsterdam, Netherlands 1017AP

January 8, 2013

Re: K121261
Trade/Device Name: asap multiscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 02, 2012
Received: November 05, 2012

Dear Ms. Scherp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121261

Device Name: *asap multiscopes*

Indications for Use:

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Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen
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(Division Sign-Off)

Division of Surgical Devices

510(k) Number ____K121261_____